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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,269	01/12/2001	Satoshi Iuchi	3914-3	9211

7590 08/13/2002

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/13/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,269

Applicant(s)

IUCHI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 9, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1 and 3-14, and Group B, SEQ ID NOS: 5 and 6, in Paper No. 16 is acknowledged. Claim 2 and SEQ ID NOS: 1, 2, 9, 10, 11, 12, 13, 14, 15 and 16 are withdrawn from consideration as being drawn to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed June 27, 2001, August 13, 2001 and December 18, 2001, Paper Nos. 6, 9 and 11, are attached to the instant Office action.

Claim Objections

Claim 3 is objected to for reciting the SEQ ID NOS of nonelected inventions. Appropriate correction is required.

Claims 5-7 are objected to because of the following informalities: the noun "transformant" modifies the noun "plant". Appropriate correction is required. It is suggested that the claims be amended to recite the adjective "transformed".

Claim 6 is objected to because of the following informalities: there is no article preceding "offspring". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant.

The specification describes only one isolated DNA molecule that encodes a protein having neoxanthin cleavage activity that improves stress tolerance when expressed in transgenic plants, the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6 (sequence listing and Example 16 pages 41-42). This does not constitute a substantial portion of the genus that comprises a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant. The claimed genus encompasses a multitude of different nucleotide sequences and proteins, including those yet to be discovered. The disclosure of only one nucleotide sequence that encode a protein having neoxanthin cleavage activity that improves stress tolerance when expressed in transgenic plants does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

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Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a transgenic plant which is the offspring or a clone of the transformant plant of claim 6.

The claimed invention lacks written description under current written description guidelines. The claim is drawn to progeny plants having undisclosed identifying characteristics whereby only one parent is known. Applicant should note that no identifying characteristics are set forth for the offspring or clones. If the claimed offspring or clone plant itself cannot be identified by characteristics clearly disclosed in the specification, then it would be impossible to determine whether or not a plant of unknown parentage is covered by the claim. Thus offspring or clone plants which are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. Absent further guidance, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genotypic or phenotypic characteristics of the offspring or clone plants obtained. Breeding and cloning techniques can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring or clones is highly unpredictable, especially in view of the fact that no identifying characteristics for the offspring or clones are disclosed in the specification or set forth in the claims. Accordingly, there is a lack of written description for the claimed offspring or clone plants, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of

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the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1 and 3-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, and a method for increasing or decreasing drought stress tolerance in *Arabidopsis* by transforming *Arabidopsis* plants with the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, does not reasonably provide enablement for other DNA molecules, or for methods of increasing or decreasing other types of stress tolerance in other species of plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant, including DNA encoding a protein comprising an amino acid sequence of SEQ ID NO:6, DNA encoding a protein comprising an amino acid sequence of SEQ ID NO:6 in which one or more amino acids are replaced, deleted, added and/or inserted, and DNA which hybridizes with a DNA comprising a nucleotide sequence of SEQ ID NO:5. The claims are also drawn to methods for increasing or decreasing stress tolerance in a plant by expressing said DNA in a plant. Additionally, the claims are drawn to plants and plant cells transformed with said DNA, including plants having increased or decreased expression of a

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gene encoding a protein having a neoxanthin cleavage activity, plants having increased or decreased abscisic acid, and plants having increased or decreased stress tolerance.

The specification discloses only one isolated DNA molecule that encodes a protein having neoxanthin cleavage activity that improves stress tolerance when expressed in transgenic plants, the *Arabidopsis* AtNCED3 DNA of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6. The specification discloses that the *Arabidopsis* AtNCED3 DNA of SEQ ID NO:5 encodes a protein having neoxanthin cleavage activity (Example 12 pages 38-39), and that expression of the *Arabidopsis* AtNCED3 DNA of SEQ ID NO:5 in a sense or antisense orientation in transgenic *Arabidopsis* plants increases or decreases AtNCED3 mRNA expression (Example 14 pages 40-41 and Figure 13), increases or decreases abscisic acid levels (Example 15 page 41 and Figure 14), and increases or decreases drought stress tolerance (Example 16 pages 41-42 and Figures 15-16) as compared to nontransformed wild type plants. The specification does not disclose other isolated DNA molecules that encodes a protein having neoxanthin cleavage activity that improves stress tolerance when expressed in transgenic plants. The specification does not disclose any DNA molecule which hybridizes with a DNA comprising a nucleotide sequence of SEQ ID NO:5 and which encodes a protein having neoxanthin cleavage activity that improves stress tolerance when expressed in a plant. The specification does not disclose which amino acids of SEQ ID NO:6 may be replaced, deleted, added and/or inserted such that the protein retains its neoxanthin cleavage activity and its ability to improve drought stress tolerance when expressed in a plant. The specification does not disclose the effect of transgene expression on any type of stress other than drought stress. The

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specification does not disclose the effect of transgene expression in any species of plant other than *Arabidopsis*.

While one of skill in the art could readily make transgenic plants comprising any known nucleotide sequence, it would require undue experimentation for one skilled in the art to determine how to express a DNA encoding a protein having neoxanthin cleavage activity in a manner that would increase or decrease tolerance to stresses other than drought, because the specification does not teach how to express a DNA encoding a protein having neoxanthin cleavage activity such that tolerance to stresses other than drought is increased or decreased. Also, while one of skill in the art could readily make amino acid replacements, deletions, additions or insertions, it would require undue experimentation for one skilled in the art to determine which amino acid replacements, deletions, additions or insertions to make in SEQ ID NO:6 such that the altered polypeptide retains neoxanthin cleavage activity and increases or decreases stress tolerance in a plant when expressed, because the specification does not teach which amino acid deletions, substitutions or additions to make. To claim all modifications without any guidance as to how inoperable embodiments can be readily identified and eliminated other than by trial and error is an initiation to experiment requiring undue experimentation. Additionally, while one of skill in the art could readily make transgenic plants expressing other DNAs encoding a protein having a neoxanthin cleavage activity, it would require undue experimentation for one skilled in the art to determine which DNA to express and at what level, because the specification does not teach which other DNAs encoding a protein having a neoxanthin cleavage activity to express, in which species of plant, and at what level, to increase or decrease stress tolerance in a plant. Furthermore, while one of skill in the art could readily

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increase or decrease the level of expression of a DNA encoding a protein having a neoxanthin cleavage activity by other methods, it would require undue experimentation for one skilled in the art to determine how much to increase or decrease the expression of that DNA, because the specification does not teach other methods of increasing or decreasing expression of a DNA encoding a protein having a neoxanthin cleavage activity in a plant such that stress resistance is increased or decreased. Additionally, in regard to claims 9 and 10, it is unclear from the claims how the same DNA could both increase and decrease the amount of abscisic acid or stress tolerance. There is insufficient guidance for one skilled in the art to determine how to obtain these increases and decreases. For example, these increases and decreases could be obtained as a result of the orientation in an expression vector of the DNA encoding a protein having neoxanthin cleavage activity, or they could be obtained as a result of the level of expression of a protein having neoxanthin cleavage activity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4 and 8 are indefinite in the recitation of "a" neoxanthin cleavage activity. It is unclear whether "a" neoxanthin cleavage activity means 1) the cleavage activity of a particular neoxanthin, or 2) a particular cleavage activity of neoxanthin. It is suggested that the claims be amended to delete the recitation of "a" before "neoxanthin cleavage activity".

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Claim 3 is indefinite in the recitation of "the stringent condition". It is unclear what conditions would yield the claimed DNA, as one skilled in the art utilizes different stringency conditions. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 4 is indefinite in the recitation of "derived". It is unclear what part of the protein is derived from *Arabidopsis* plants. It is suggested that the claim be amended to recite "obtained".

Claims 5 and 13 are indefinite in the recitation of "carrying". It is unclear how the plant cell carries the DNA of claim 1. It is suggested that the claims be amended to recite "comprising" or "containing".

Claim 8 is indefinite in the recitation of "gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers, promoters, and introns. It is suggested that the claim be amended to recite "isolated DNA", "isolated polynucleotide" or "isolated nucleic acid".

Claim 8-10 are indefinite in the recitation of "its wild type". It is unclear what "its" and "wild type" refer to.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 14 omits the step of increasing or decreasing stress tolerance in a plant, as recited in the preamble of the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 3-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant. The claims are also drawn to transgenic plants, plant cells and plant propagation material carrying said DNA, including transgenic plants having increased expression of a gene encoding neoxanthin cleavage activity, transgenic plants having an increased or decreased amount of abscisic acid, and transgenic plants having an increased or decreased stress tolerance.

A DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant would occur in nature. Similarly, a transgenic plant would also carry such DNA, since any plant would presumably have an endogenous DNA encoding a protein having neoxanthin cleavage activity. It is suggested that claim 1 be amended to recite "isolated DNA", "isolated polynucleotide" or "isolated nucleic acid" to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan et al. (Accession No. ZMU95953, 04 July 1997, Applicant's IDS).

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The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant.

Tan et al. teach a DNA encoding a protein having neoxanthin cleavage activity. Although Tan et al. do not explicitly teach improving stress tolerance in a plant, such a function would be an inherent property of the DNA of Tan et al. Furthermore, while Tan et al. do not teach a protein comprising an amino acid sequence of SEQ ID NO:6, the DNA taught by Tan et al. comprises an amino acid sequence in which one or more amino acids in SEQ ID NO:6 are replaced, deleted, added and/or inserted, as part (b) of claim 3 reads on any DNA encoding a protein having neoxanthin cleavage activity.

Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jaglo-Ottosen et al. (Science, 3 April 1998, Vol. 280, pages 104-106).

The claim is drawn to a transgenic *Arabidopsis* plant which is the offspring or a clone of the transformant plant of claim 6.

Jaglo-Ottosen et al. teach a transgenic *Arabidopsis* plant comprising a DNA encoding the transcriptional activator CBF1 (page 104 column 3 first full paragraph). There are insufficient identifying characteristics set forth in the claims to distinguish the claimed transgenic plants from transgenic plants of the prior art. The claims do not specifically recite a plant whereby all of the identifying characteristics of the parent plant are retained. The breeding and cloning techniques used to produce the claimed plants can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring

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or clones is highly unpredictable. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection *supra*).

Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of any prior art that teaches transgenic *Arabidopsis* plants. See *in re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process of making the product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al. (Accession No. ZMU95953, 04 July 1997, Applicant's IDS).

The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity. The claims are also drawn to transgenic plants, plant cells and plant propagation material

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carrying said DNA. Additionally, the claims are drawn to a method for producing a transgenic plant by introducing said DNA into a plant cell.

Tan et al. teach a DNA encoding a protein having neoxanthin cleavage activity.

Tan et al. do not teach transgenic plants, plant cells and plant propagation material, or a method for producing a transgenic plant.

Given that the prior art of Tan et al. teaches a DNA encoding a protein having neoxanthin cleavage activity, and given that plant transformation technology was well known in the art at the time of Applicant's invention, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the DNA encoding a protein having neoxanthin cleavage activity taught by Tan et al. to make a transgenic plant comprising a DNA encoding a protein having neoxanthin cleavage activity, without any surprising or unexpected results. Furthermore, expression in a transgenic plant of the DNA encoding a protein having neoxanthin cleavage activity would inherently cause a change in the amount of abscisic in the plant and a change in the amount of stress tolerance exhibited by the plant. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al. (Accession No. ZMU95953, 04 July 1997, Applicant's IDS) in view of Schwartz et al. (Science, 20 June 1997, Vol. 276, pages 1872-1874, Applicant's IDS).

The claims are drawn to a DNA encoding a protein having neoxanthin cleavage activity for improving stress tolerance in a plant. The claims are also drawn to transgenic plants, plant

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cells and plant propagation material carrying said DNA, including transgenic plants having increased or decreased expression of a gene encoding neoxanthin cleavage activity, transgenic plants having an increased or decreased amount of abscisic acid, and transgenic plants having increased or decreased stress tolerance.

Tan et al. teach a DNA encoding a maize protein (VP14) having neoxanthin cleavage activity.

Tan et al. do not teach transgenic plants, plant cells and plant propagation material, a method for producing a transgenic plant, or a method for increasing or decreasing stress tolerance in a plant.

Schwartz et al. teach that a maize protein having neoxanthin cleavage activity (VP14) functions in the biosynthesis of abscisic acid, a plant growth regulator involved in regulating plant stress tolerance.

Given the teaching of Schwartz et al. that the maize protein VP1 has neoxanthin cleavage activity and functions in the biosynthesis of abscisic acid, given that it was well known in the art at the time of Applicant's invention that abscisic acid functions to regulate stress tolerance, and given that plant transformation technology was well known in the art at the time of Applicant's invention, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the DNA encoding the maize protein VP1 taught by Tan et al. to make a transgenic plant comprising said DNA, for the purpose of increasing or decreasing the amount of abscisic acid in a plant, and for the purpose of increasing or decreasing stress tolerance in a plant, without any surprising or unexpected results. Thus, the claimed invention

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would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, absent evidence to the contrary.

Remarks

No claim is allowed.

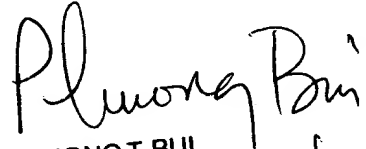
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
August 10, 2002


PHUONG T. BUI
PRIMARY EXAMINER 8/12/02